

TAB 1

Docket No. 244818US001P

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:

Veronique FERRARI, et al.

EXAMINER: J. VENKAT

SERIAL NO.: 10/733,467

FILED: DECEMBER 12, 2003

GROUP ART UNIT: 1615

FOR: COSMETIC COMPOSITION CONTAINING
A POLYORGANOSILOXANE POLYMER

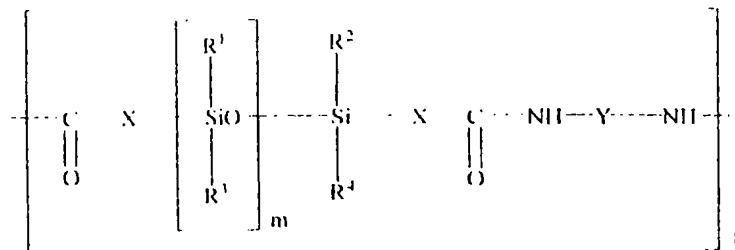
DECLARATION UNDER 37 C.F.R. 1.132

COMMISSIONER FOR PATENTS
ALEXANDRIA, VA 22313

SIR: **LEVY Florence**

I, (to be completed), hereby declare:

1. Nylon 611/Dimethicone is a commercially available copolymer. It is marketed by Dow Corning under the designation Dow Corning® 2-8178. A copy of a Dow Corning product information sheet for this product obtained from the internet is attached at Tab A.
2. Nylon 611/Dimethicone corresponds to formula (III) in the above-identified application. More specifically, formula (III) in the above-identified application is,



(III)

In correspondence with Nylon 611/Dimethicone, ^{R3}~~R1-R4~~ are methyl groups attached to silicon atoms to form the dimethicone unit within the polymer. "M" represents the number of repeating dimethylated silicon units in the dimethicone unit within the polymer (less 1), or the "degree of polymerization (DP)" of the dimethicone unit. The final dimethylated silicon unit of the dimethicone unit corresponds to the Si atom to which ^{R2}~~R3~~ and R4 is attached.

3. "X" and "Y" correspond to alkylene groups. In accordance with standard nylon nomenclature, "nylon 611" contains one alkylene group having 6 carbon atoms, and a second alkylene group containing 11 carbon atoms. In accordance with standard silicon technology, the final dimethylated silicon unit of the dimethicone unit is attached to the alkylene group identified as "X" through oxygen.

4. In the above-identified application, the exemplified compositions all contain Nylon 611/Dimethicone. The polymers used in the exemplified compositions include, for example, the following:

A. Dow Corning DC 2-8179 (DP = 100) (example 2);

B. Example 3 of U.S. patent 5,981,680 (DP = 15) (example 9) (which corresponds to the copolymer in Dow Corning DC 2-8178);

C. Example 3 of U.S. patent 5,981,680 (DP = 100) (example 18)(which corresponds to the copolymer in Dow Corning DC 2-8179); and

D. "Silicone polyamide" (DP = 45) (example 21)(which was a nylon 611/dimethicone copolymer having a DP of 45.

5. The difference between the copolymer in Dow Corning's 2-8178 and the identified copolymer products used in the exemplified compositions discussed above, if any, does not relate to the polymers *per se* -- all polymers are Nylon 611/dimethicone polymers. Rather, the difference relates to degrees of polymerization within the polymer.

6. The undersigned petitioner declares further that all statements made herein of her own knowledge are true and that all statements made on information and belief are believe to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

7. Further deponent sayeth not.

LEVY Florence
Name


Signature

17.03.2009
Date

TAB A

DOW CORNING® 2-8178 Gellant

FEATURES

- Clear structurant or thickener
- Compatible with organic or silicone and organic formulations
- Modifies the texture and skin feel of anhydrous or emulsion based cosmetics and toiletries
- Film former
- Semi-occlusive (See Figure 1)
- Not tested on animals

BENEFITS

- Provides a unique non-tacky, dry smooth skin feel with emolliency
- Increases absorption of water-in-oil emulsions with less greasiness compared to organic waxes or petrolatum
- Enhances the appearance of skin, matte or shine, depending on the formulation
- Improves color retention on hair
- Improves payout and wash off resistance
- Minimizes color transfer in cosmetic applications
- Improves suspension of pigments in color formulations
- Potential use as film former for reduced appearance of fine lines
- Potential for enhanced fragrance delivery

COMPOSITION

- Approximately
88% Nylon-611/Dimethicone Copolymer
in 12% PPG-3 Myristyl Ether

Silicone Polyamide

**INCI Name: Nylon-611/Dimethicone Copolymer (and)
PPG-3 Myristyl Ether**

APPLICATIONS

- Color cosmetics
- Skin care - facial moisturizers, nourishing & anti-aging
- Sun care
- Hair care - conditioners, colorants & styling

TYPICAL PROPERTIES

Specification writers: These values are not intended for use in preparing specifications. Please contact your local Dow Corning sales representative prior to writing specifications on this product.

Appearance: Product supplied as a straw-colored granular solid
Melt point: 85-105°C (185-221°F)

CTM*	Property	Unit	Value
0080	Color, gardner		0-6
0182A	Vinyl	%	0.7 maximum
0208	Non-volatile content 0.5G/0.5H/250°C (482°F) Al Cup	%	85-95
0806	SiH	ppm	100 maximum
0874	Melt viscosity HAT/SC4-27/140°C (284°F)	cP	750-5000
9800	Molecular weight	Daltons	50,000-85,000

* CTM: Corporate Test Method, copies of CTMs are available on request.

DESCRIPTION

DOW CORNING 2-8178 Gellant is a unique (AB)_n silicone organic Copolymer. Due to the hydrogen bonding between the amide groups, this technology has the ability to form clear and opaque systems that range from liquids to rigid solids.

By varying the use levels of the DOW CORNING 2-8178 Gellant and selecting different types and ratios of the silicone and organic components, this technology offers maximum flexibility to modify the rheology, skin feel, and the resulting film properties of color cosmetics, skin care, and hair care applications.

This technology and its application in personal care have been patented by Dow Corning and by some leading cosmetic manufacturers. Based on the current agreements, this technology is not currently available from Dow Corning for antiperspirant and deodorant applications. Relating to use in other cosmetic applications, additional information on the Intellectual Property situation is available from Dow Corning.

CHEMICAL STRUCTURE

See Figure 2.

HOW TO USE

Step 1: Estimate the amount of gellant required in the final application.

- For solids – use 10-30%
- For creams and gels, use 3-5%
- To enhance skin feel and film properties, use 1-3%.

Step 2: Heat the DOW CORNING 2-8178 Gellant until melted. Add desired organic and silicone oil phase components to produce a uniform mixture. Ensure that safe handling procedures are used if handling these ingredients above their flash points.

Refer to Table 1 for compatibility information on DOW CORNING 2-8178 Gellant with selected ingredients.

Figure 3 summarizes the compatibility and clarity of various compositions based on DOW CORNING 2-8178 Gellant, DOW CORNING® 2-1184 Fluid and Finsolv® TN from Finetex, Inc.

The clarity and the hardness of the resulting anhydrous blend will be influenced by the type of organic selected and the concentration of the DOW CORNING 2-8178 Gellant in the formulation.

Figure 4 demonstrates that 10% 2-8178 Gellant will produce a clear, rigid solid with many common esters, fatty alcohols and fatty acids. For formulations containing hydrocarbon oils, the hardness of the blend will increase as the use level of gellant increases (Refer to Figure 5).

Step 3: Use the desired blend as a base for anhydrous or emulsion based systems using standard techniques. For best results, heat the oil and water phase to approximately the same temperature prior to emulsification. Cool and incorporate temperature sensitive ingredients as needed.

HANDLING PRECAUTIONS

Product safety information required for safe use is not included. Before handling, read product and safety data sheets and container labels for safe use, physical and health hazard information. The material safety data sheet is available on the Dow Corning website at www.dowcorning.com. You can also obtain a copy from your local Dow Corning sales representative or Distributor or by calling your local Dow Corning Global Connection.

USABLE LIFE AND STORAGE

When stored at or below 50°C (122°F) in the original unopened containers, this product has a usable life of 24 months from the date of production.

PACKAGING

This product is available in 10kg pails and 100kg fiber drums.

Samples are available in 0.2kg tubs.

LIMITATIONS

This product is neither tested nor represented as suitable for medical or pharmaceutical uses.

HEALTH AND ENVIRONMENTAL INFORMATION

To support Customers in their product safety needs, Dow Corning has an extensive Product Stewardship organization and a team of Product Safety and Regulatory Compliance (PS&RC) specialists available in each area.

For further information, please see our website, www.dowcorning.com or consult your local Dow Corning representative.

LIMITED WARRANTY INFORMATION - PLEASE READ CAREFULLY

The information contained herein is offered in good faith and is believed to be accurate. However, because conditions and methods of use of our products are beyond our control, this information should not be used in substitution for customers' tests to ensure that Dow Corning's products are safe, effective, and fully satisfactory for the intended end use. Suggestions of use shall not be taken as inducements to infringe any patent.

Dow Corning's sole warranty is that the product will meet the Dow Corning sales specifications in effect at the time of shipment.

Your exclusive remedy for breach of such warranty is limited to refund of purchase price or replacement of any product shown to be other than as warranted.

DOW CORNING SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR MERCHANTABILITY.

DOW CORNING DISCLAIMS LIABILITY FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES.

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Table 1: DOW CORNING 2-8178 Gellant is compatible with various organic fluids and can be used to produce gels to rigid solids with various ratios of silicone and organic fluids. For optimum skin feel, try using a volatile silicone carrier such as DOW CORNING® 245 Fluid.

<i>Organic fluid</i>	<i>% 245 Fluid</i>	<i>Organic component</i>	<i>Appearance (room temperature)</i>	<i>Structure</i>
Caprylic/capric triglyceride	30-45%	45-60%	Clear to translucent	Gel to solid
PPG 3 myristyl ether	10-55%	35-80%	Clear to translucent	Gel to solid
Finsolv® TN (C ₁₂₋₁₅ alkyl benzoate)	55%	35%	Clear to translucent	Gel to solid
Isostearyl alcohol	15-75%	15-75%	Clear to translucent	Gel to solid
Oleyl alcohol	15-75%	15-75%	Clear to translucent	Gel to solid
Cetyl alcohol	15-75%	15-75%	Opaque	Opaque solid
Stearyl alcohol	15-75%	15-75%	Opaque	Opaque solid
Stearic acid	15-75%	15-75%	Opaque	Opaque solid
Oleic acid	15-75%	15-75%	Clear to translucent	Gel to solid
Crodamol OS	15-25%	65-75%	Clear to translucent	Gel to soft solid
Isostearyl neopentanoate	5-20%	70-85%	Clear to translucent	Very soft, granular gel

To further modify the properties of the resulting anhydrous blend, substitute other silicone carriers in place of DOW CORNING® 245 Fluid including DOW CORNING® 2-1184 Fluid or DOW CORNING® 556 Fluid. Please note that compatibility ratios may vary slightly based on typical lot-to-lot variation of DOW CORNING 2-8178 Gellant.

DOW CORNING 2-8178 Gellant is also compatible with ethyl alcohol (200 proof) at concentrations up to 80% gellant and 20% ethyl alcohol. In order to obtain these mixtures, continuous movement of the solution may be required for up to 48 hours.

Figure 1.

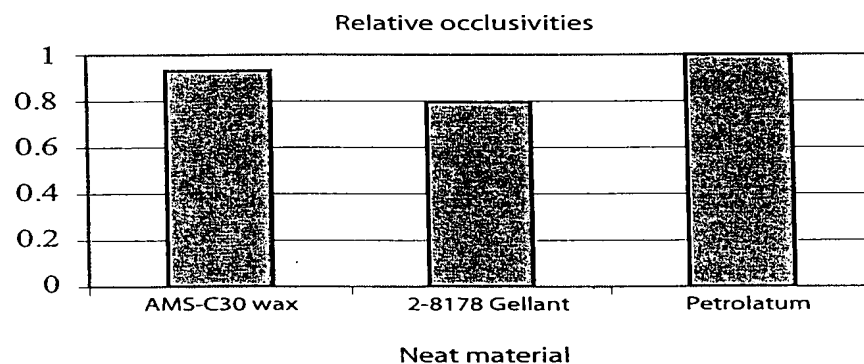


Figure 2: DOW CORNING 2-8178 Gellant chemical structure.

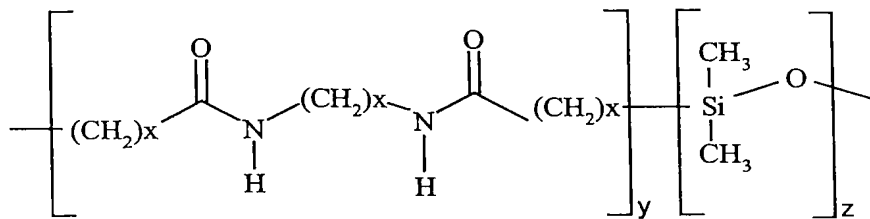
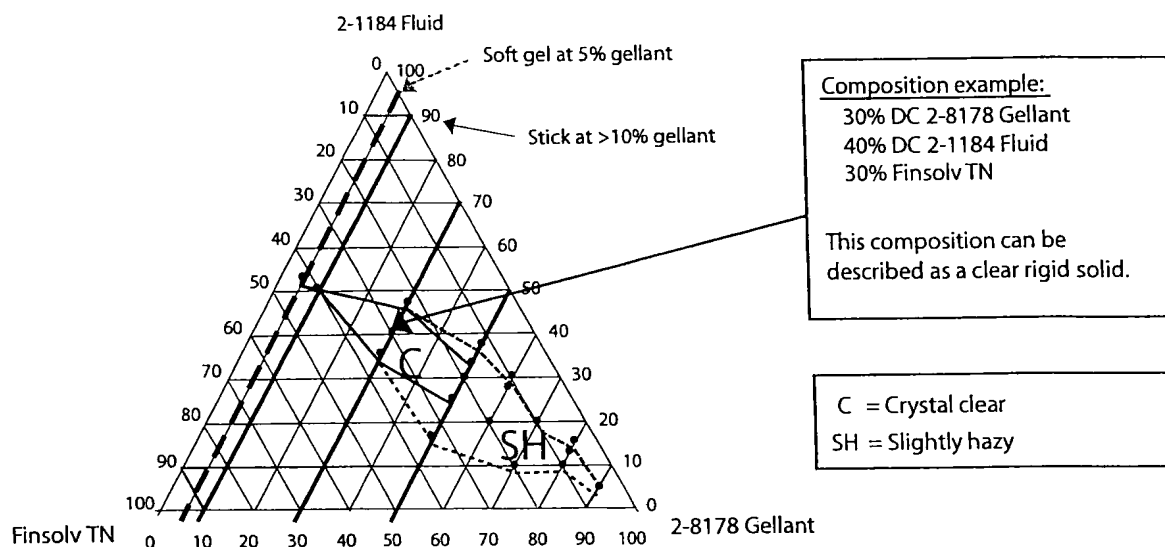
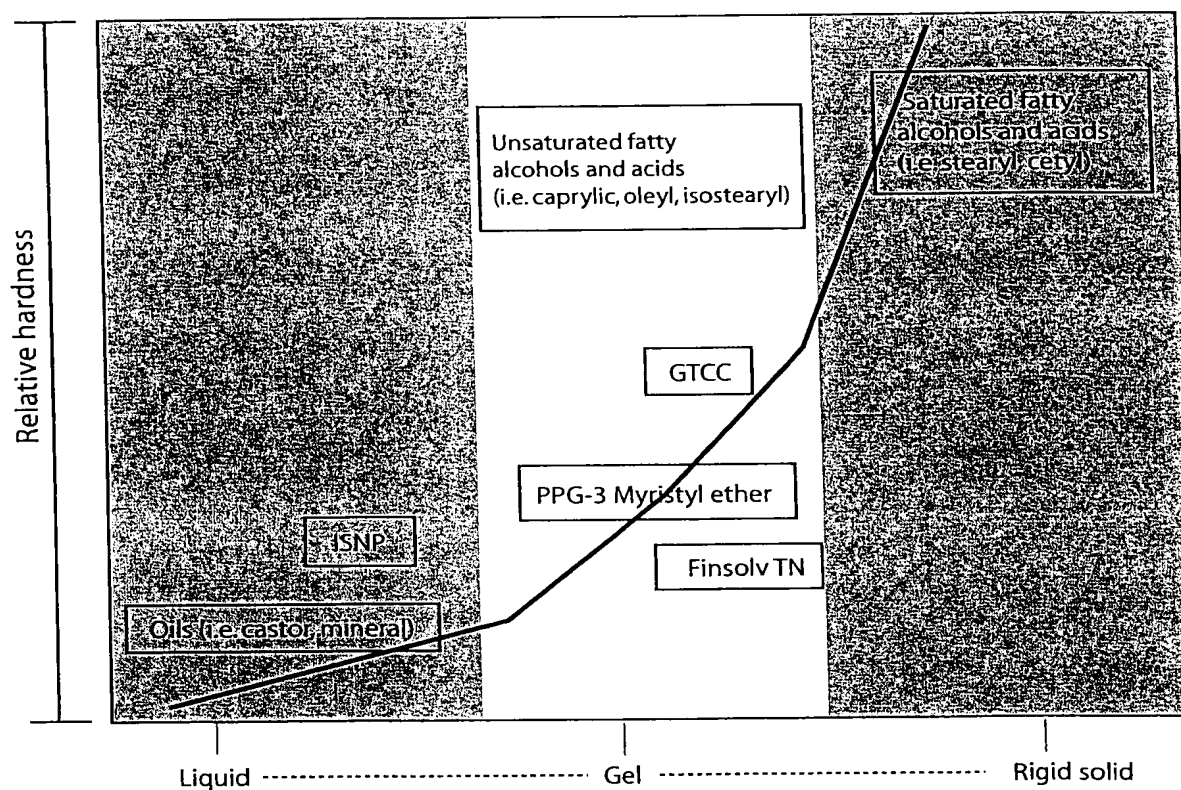


Figure 3: Ternary diagram of DOW CORNING 2-8178 Gellant, DOW CORNING 2-1184 Fluid and Finsolv TN.



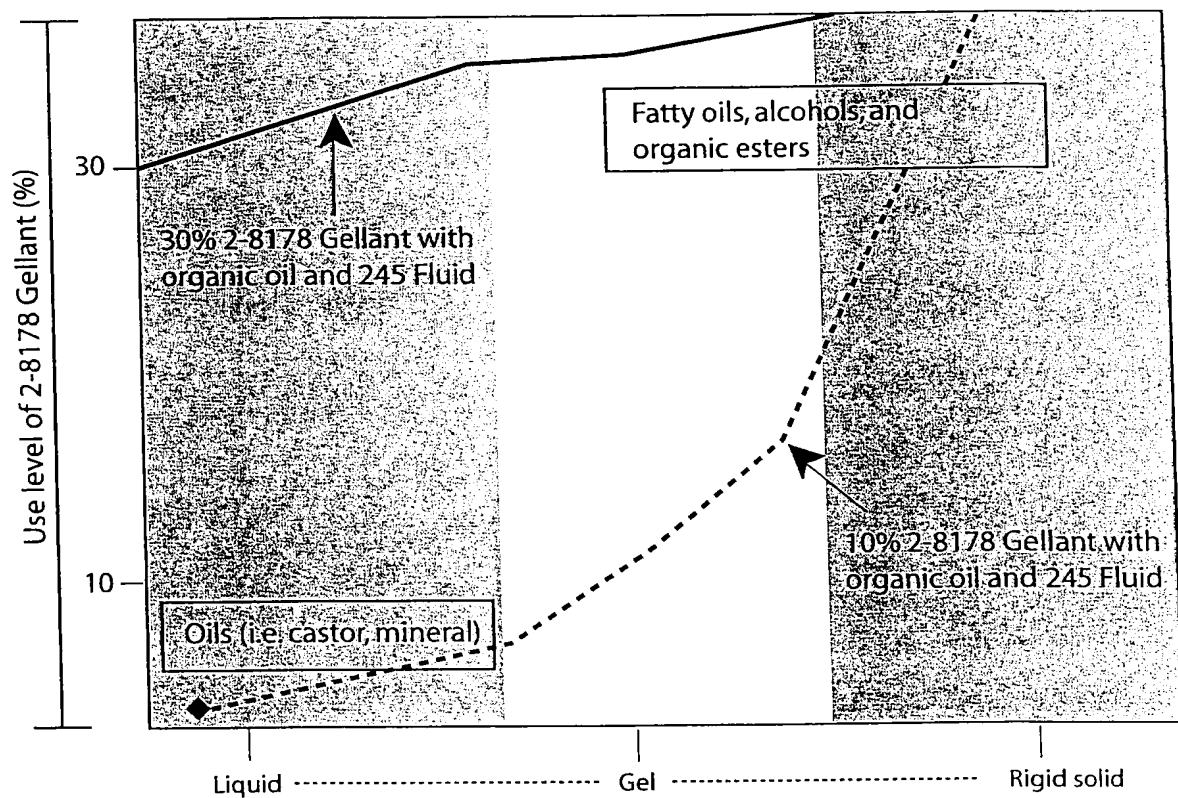
Note: For concentrations at >50% 2-8178 Gellant, the three-component blend will appear slightly hazy.

Figure 4. The Effect of the organic carrier on hardness at 10% Gellant in Cyclomethicone.



10% 2-8178 Gellant in various ratios of 245 Fluid

Figure 5. The impact of 2-8178 Gellant use level on hardness.



Increasing the level of 2-8178 will increase the hardness of mixtures containing oils.

TAB 2

BACKGROUND OF THE INVENTION

In the hair and skin care area, the trend is toward spending less time on personal hygiene, and a need exists for cosmetic products with multiple benefits. Examples in hair care include shampoos that provide cleaning, conditioning and light style retention, hair conditioners that provide conditioning and light style retention, and hair sprays and mousses that provide flexible hold and soft feel.

Silicone-organic block and graft copolymers are well known. These copolymers combine thermoplastic properties, which give them solubility and strength, with elastic properties, due to the flexible silicone chain. The combination of silicone and organic moieties give the copolymers flexibility and shape retention.

Related art:

U.S. Pat. No. 5,120,531

U.S. Pat. No. 5,500,209

U.S. Pat. No. 5,243,010

U.S. Pat. No. 5,272,241

U.S. patent application Ser. No. 08/790,351 filed Jan. 24, 1997, now published as WO97/36572 assigned to The Mennen Company.

US Pat. No. 6,051,216, the contents of which are incorporated herein by reference in their entirety, discloses siloxane-based polyamides polymers which can be used as gelling agents to thicken cosmetic compositions, which polymers are compatible with volatile and/or non-volatile silicone liquids. In general, the siloxane-based polyamides contain both siloxane groups and amide groups that thicken compositions containing silicone fluids (volatile and/or non-volatile silicone fluids). The siloxane-based polyamides are non-flowable solids at room temperature, and dissolve in a fluid that contains silicone at a temperature of 25-160°C., to form a translucent or clear solution at a temperature in this range. With regard to the siloxane units in the siloxane-based polyamides, the siloxane units must be in the main or backbone chain but can also optionally be present in branched or pendent chains.

US Pat. No. 5,981,680, the contents of which are incorporated herein by reference in their entirety, discloses improved siloxane-based polyamide copolymers and an improved method for making them, which copolymers can be used as gelling agents to thicken cosmetic compositions and are very useful in the present invention.

Thermoplastic elastomeric silicone-polyamide copolymers ("silicone-polyamide copolymers") have the desired flexibility, strength, and elastic properties and is readily soluble and/or dispersible in alcohol and other organic and silicone solvent systems. The polysiloxane blocks modify their surface properties to give

them a smooth, slippery feel. The silicone-polyamide copolymers are easy to formulate into a wide variety of vehicles. The silicone-polyamide copolymers thicken silicone and other organic solvent systems, and can be used to thicken hair and skin care formulations. Furthermore, these materials provide hair care compositions which leave the hair feeling natural, i.e. not very stiff or sticky.

In addition to the hair care benefits provided by silicone-polyamide copolymers, it has been found that these materials are also useful for incorporation into a wide variety of cosmetic and pharmaceutical composition for topical application to the skin. These copolymers provide topical compositions that are more easily and uniformly spread upon the skin, which feel good upon the skin, and yet which are highly substantive and film forming. Furthermore, these copolymers provide topical compositions that are useful for delivering a wide variety of fragrance, cosmetic and pharmaceutical actives to the skin. The film forming and barrier properties of the copolymers provide compositions that give durability to cosmetic and pharmaceutical actives. The need exists for sustained fragrance release from personal care products. Fragrance encapsulation serves this need, but the processing is expensive. The silicone-polyamide copolymers are compatible with most fragrance components and are film forming, thereby acting as a barrier to fragrance release in the final personal care formulation after the volatile components have evaporated.

It is an object of the present invention to provide novel hair care compositions containing the silicone-polyamide copolymers having improved styling and/or hold properties and having improved aesthetics and longer lasting fragrance release.

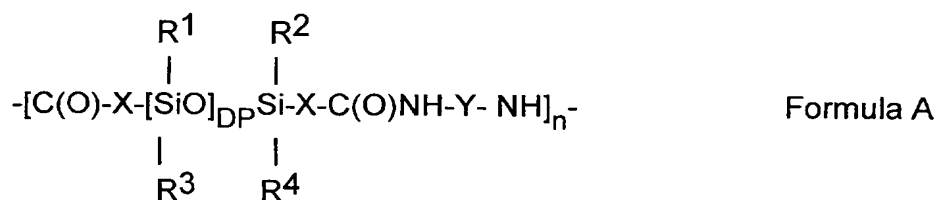
It is another object of the present invention to provide novel topical cosmetic and pharmaceutical compositions containing the silicone-polyamide copolymers useful for delivering a wide variety of cosmetic materials and pharmaceutical actives to the skin, and having improved aesthetics and longer lasting fragrance release.

These and other objects will become readily apparent from the detailed description that follows.

DETAILED DESCRIPTION OF THE INVENTION

The foregoing objects are achieved by the present invention which comprises forming and using novel silicone-polyamide copolymers as thickening agents, film forming agents and durability enhancers to formulate cosmetic compositions such as hair care compositions and skin care compositions. The selected silicone-polyamide copolymers described herein exhibit superior performance when used to form cosmetic compositions.

The silicone-polyamide copolymers of this invention are multiples of a unit represented by the following Formula A:



where:

(1) The degree of polymerization (DP) is 1-700, preferably 10-500, and more preferably 15-100. DP represents an average value for degree of polymerization of the siloxane units in the polymer with greater or lesser DP values centered around the indicated DP value.

(2) n is 1-500, particularly 1-100, and more particularly 4-25.

(3) X is a linear or branched chain alkylene having 1-30 carbons, particularly 3-10 carbons, and more particularly 10 carbons.

(4) Y is a linear or branched chain alkylene having 1-40 carbons, particularly 1-20 carbons, more particularly 2-6 carbons, and especially 6 carbons wherein

(a) The alkylene group may optionally and additionally contain in the alkylene portion at least one of (i) 1-3 amide linkages; (ii) a C5 or C6 cycloalkane; or (iii) phenylene, optionally substituted by 1-3 members which are independently C1-C3 alkyls; and

(b) The alkylene group itself may optionally be substituted by at least one of (i) hydroxy; (ii) a C3-C8 cycloalkane; (iii) 1-3 members which are independently C1-C3 alkyls; phenyl, optionally substituted by 1-3 members which are independently C1-C3 alkyls; (iv) a C1-C3 alkyl hydroxy; or (v) a C1-C6 alkyl amine; and

(c) Y can be Z where Z is T(R²⁰)(R²¹)(R²²) where R²⁰, R²¹ and R²² are each independently linear or branched C1-C10 alkenes; and T is CR in which R is hydrogen, the group defined for R¹-R⁴, or a trivalent atom such as N, P and Al.

(5) Each of R¹-R⁴ (collectively "R") is independently methyl, ethyl, propyl, isopropyl, a siloxane chain, or phenyl, wherein the phenyl may optionally be substituted by 1-3 members, which are methyl or ethyl. More particularly, R¹-R⁴ are methyl or ethyl, especially methyl.

(6) X, Y, DP, and R¹-R⁴ may be the same or different for each polyamide unit.

Also, the polyamides must have a siloxane portion in the backbone and optionally may have a siloxane portion in a pendant or branched portion.

The term "alcohol or organic or silicone solvent soluble or dispersible" as used herein means that these copolymers are either freely soluble in or dispersible (as a stable suspension) in at least one alcohol or organic or silicone solvent at a

concentration of at least 0.1 wt. %. By "soluble" is meant that the copolymer is soluble in the solvent or solvents at 25°C. By "dispersible" is meant that the copolymer forms a stable, uniform suspension (without the addition of further materials such as emulsifiers) when combined with the solvent or solvents.

The cosmetic compositions according to the present invention include at least one solvent acceptable for personal care formulations, the silicone-polyamide copolymer and at least one cosmetically active material, incorporated in the composition in an amount sufficient to have a functional effect.

Illustratively, and not to be limiting, such solvents can include esters (for example, isopropyl myristate and C12-15 alkyl lactate), silicone fluids (for example, cyclomethicone, dimethicone), ethanol, isopropanol, guerbet alcohols having 8-30 carbons, particularly 12-22 carbons (for example, isolauryl alcohol, isocetyl alcohol, isostearyl alcohol), fatty alcohols (for example, stearyl alcohol, myristyl alcohol, oleyl alcohol), and ethoxylated and propoxylated alcohols (for example, the polyethylene glycol ether of lauryl alcohol that conforms to the formula $\text{CH}_3(\text{CH}_2)_{10}\text{CH}_2(\text{OCH}_2\text{CH}_2)_b\text{OH}$ where b has an average value of 4 (also called laureth-4). PPG-14 butyl ether, where the "PPG-14" portion is the polymer of propylene oxide that conforms generally to the formula $\text{H}(\text{OCH}_2\text{C}(\text{CH}_3)\text{H})_c\text{OH}$, where c has an average value of 14, or PPG-3 myristyl ether which is the polypropylene glycol ether of myristyl alcohol that conforms to the formula $\text{CH}_3(\text{CH}_2)_{12}\text{CH}_2(\text{OCH}(\text{CH}_3)\text{CH}_2)_d\text{OH}$ where d has an average value of 3. Mixtures of solvents can also be used. Of course, the silicone-polyamide copolymers must be soluble in the solvent system, at least at elevated temperatures, as described in U.S. Pat. No. 5,500,209.

Actives include, but are not limited to vitamins, fragrances, sunscreens, and antibacterials (antimicrobials). For example, where the composition is a composition to protect skin from the sun, a sufficient amount of a sun-screening agent is provided in the composition such that when the composition is applied to the skin, the skin is protected from the harmful effects of the sun (for example, is protected from ultraviolet rays from the sun).

The cosmetic compositions of the present invention can also be utilized to form hair and skin care compositions having multiphase systems, such multiphase systems having a polar (for example, water) phase and an oil phase. In order to provide a clear multiphase system, refractive indices of the oil and polar phases desirably should be matched, as done conventionally in the art.

Cosmetic compositions according to the present invention can easily be manufactured by methods known to those skilled in the art such as by using known mixing procedures. Base compositions according to the present invention can be made by mixing the various components at an elevated temperature (that is, by heating and mixing the various components) and then cooling in order to form the thickened composition, for example, as a cream or lotion. For cosmetic

compositions, the additional ingredients are added using techniques and at times in the manufacturing process as are known to those in the art. Desirably, any volatile components (such as fragrances) are added to the mixture at a relatively late stage of the mixing, so as to limit volatilization of the volatile components.

An illustrative and non-limiting example of the present invention is as follows. The silicone-polyamide copolymer can be dissolved in the silicone fluid, for example, at elevated temperatures (for example, up to 160 degrees C.) so as to form a solution. It is preferred that the solution is not heated too long or at too high a temperature, since such disadvantageously may cause the solution to be colored (rather than colorless). The cosmetic active can be added to the solution of silicone fluid and silicone-polyamide copolymer and mixed so as to be homogeneously distributed in the product.

For example, the silicone fluids or other organic solvent and silicone-polyamide copolymers can be mixed at elevated temperatures so as to dissolve the polymer in the silicone fluids, with cosmetically active ingredients being added to the mixture of silicone fluids and polymer. In the case where an aqueous phase is included, an emulsion is the result.

Where the product is a cream product, the molten product, at elevated temperatures, can be poured into dispensing containers and allowed to cool and thicken therein.

In the hair and skin care compositions, the silicone-polyamide copolymer can be used in an amount of 0.5-80 percent by weight, more particularly 1-30 percent by weight and most particularly 2-20 percent by weight. It is preferred that the silicone-polyamide copolymer not exceed 50 percent by weight of the composition. The alcohol, silicone or organic solvent is in the range of 0-50 percent by weight, more particularly 1-20 percent by weight, even more particularly 2-15 percent by weight. Optionally, additional solvents, mixtures of solvents or cosmetic additives may be added to the base composition. Suitable additional solvents are those which are either themselves or in mixtures with other solvents miscible in the originally selected alcohol, silicone or organic solvent.

Compositions according to the present invention optionally include emollients. Illustrative emollients, which are not limiting of the present invention, would include guerbet alcohols (such as isocetyl alcohol or isostearyl alcohol); esters (such as isopropyl palmitate, isopropyl isostearate, octyl stearate, hexyl laurate and isostearyl lactate); a liquid mixture of hydrocarbons which are liquids at ambient temperatures (such as petroleum distillates and light mineral oils); ethanol; volatile and non-volatile silicone oils, highly branched hydrocarbons, and non-polar carboxylic acids. The emollients can be included in the compositions of the present invention in amounts within the range of 0.01-70%, preferably 0.1-25%, by weight, of the total weight of the composition.

Throughout the specification and claims, all percents are in percents by weight based on the cosmetic composition.

Because these copolymers melt above room temperature, these copolymers are useful in hair styling and setting compositions. Without being limited by theory, it is believed that when these copolymers are subjected to temperatures above these melting points, they are capable of flowing and can provide flexibility during the styling process (e.g., when curling irons, blow driers, and other heat sources are applied to the hair). Upon cooling of the copolymer to room temperature, the copolymer is typically below the melting temperature and the copolymer possesses structural rigidity, and yet has flexibility from the polysiloxane blocks, and can provide a strong, yet flexible, hair hold or style retention. Additionally, the siloxane blocks of the copolymers provide a smooth silky, feel and shine to the hair.

Furthermore, at skin temperatures, these copolymers would be at a temperature that is essentially below their melt temperature. The copolymers can enhance the film forming properties of skin care compositions, and provide benefits such as better and more even distribution upon the skin, faster absorbance of the composition, and protection of active ingredients from easily rubbing or washing off the skin.

Hair Care and Topical Skin Care Compositions

The silicone-polyamide copolymers of the present invention can be formulated into a wide variety of product types, including mousses, gels, lotion, cream, tonics, sprays, shampoos, sunscreens, anti-acne preparations, topical analgesics, mascaras, and the like. The carriers and additional components required to formulate such products vary with product type and can be routinely chosen by one skilled in the art. The following is a description of some of these carriers and additional components.

Carriers

The hair care compositions of the present invention can comprise a carrier, or a mixture of such carriers, which are suitable for application to the hair. The carriers are present at from about 0.5% to about 99.5%, preferably from about 5.0% to about 99.5%, more preferably from about 10.0% to about 98.0%, of the composition. As used herein, the phrase "suitable for application to hair" means that the carrier does not damage or negatively affect the aesthetics of hair or cause irritation to the underlying skin.

Where the hair care compositions are conditioners and rinses, the carrier can include a wide variety of conditioning materials, such as hydrocarbons, silicone fluids, and cationic materials. Where the hair care compositions are shampoos, the carrier can include surfactants, suspending agents, thickeners etc. Various additional components useful in hair care compositions are described in U.S.

Patent No. 4,387,090, to Bolich, Jr. issued June 7, 1983; which are incorporated by reference herein. Some of these additional components are described below.

Topical Skin Care Compositions

The topical cosmetic and pharmaceutical compositions of the present invention can comprise a carrier. The carrier should be "cosmetically and/or pharmaceutically acceptable", which means that the carrier is suitable for topical application to the skin, has good aesthetic properties, is compatible with the silicone-polyamide copolymers of the present invention and any other components, and will not cause any untoward safety or toxicity concerns.

The carrier can be in a wide variety of forms. For example, emulsion carriers, including, but not limited to, oil-in-water, water-in-oil, water-in-oil-in-water, and oil-in-water-in-silicone emulsions, are useful herein.

Other suitable topical carriers include anhydrous liquid solvents such as oils, alcohols, and silicones (e.g., mineral oil, ethanol, isopropanol, dimethicone, cyclomethicone, and the like); aqueous-based single phase solvents (e.g., where the viscosity of the solvent has been increased to form a solid or semi-solid by the addition of appropriate gums, resins, waxes, polymers, salts, and the like). Examples of topical carrier systems useful in the present invention are described in the following four references all of which are incorporated herein by reference in their entirety: "Sun Products Formulary" Cosmetics & Toiletries, vol. 105, pp. 122-139 (December 1990); "Sun Products Formulary", Cosmetics & Toiletries, vol. 102, pp. 117-136 (March 1987).

Preferred cosmetically and/or pharmaceutically acceptable topical carriers include hydro-alcoholic systems and oil-in-water emulsions. When the carrier is an oil-in-water emulsion, the carrier can include any of the common excipient ingredients for preparing these emulsions. Additional components useful in formulating these topical compositions are further described below.

Additional Components

A wide variety of additional components can be employed in the hair care and topical skin compositions herein. Non-limiting examples include the following:

The compositions of the present invention, especially the topical skin care compositions, can comprise a safe and effective amount of a pharmaceutical active.

Useful pharmaceutical actives in the compositions of the present invention include anti-acne drugs, non-steroidal anti-inflammatory drugs (NSAIDS), antipruritic drugs, and antimicrobial drugs (antibacterial, antifungal, antiprotozoal and antiviral drugs).

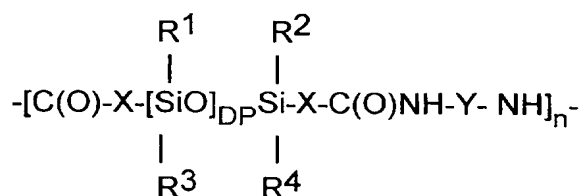
Also useful herein are sunscreens agents. A wide variety of sunscreens agents are described in Chapter VIII, pages 189 et seq., of Cosmetics Science and Technology.

Also useful in the present invention are sunless tanning agents, skin bleaching (or lightening) agents, anti-dandruff actives such as zinc Pyrithione, humectant or moisturizing materials surfactants such as anionic, nonionic, cationic, zwitterionic and amphoteric surfactants, and a carboxylic copolymer thickener.

EXAMPLES

The following table illustrates compositions of silicone-polyamide copolymers shown to be very useful in the examples of hair and skin care compositions. The silicone DP represents the average number of $\text{Si}(\text{CH}_3)_2\text{O}$ units in each silicone block within the silicone-polyamide multiblock copolymer. The molecular weights of the silicone-polyamide copolymers were measured using Gel Permeation Chromatography.

The silicone-polyamide copolymers ("Copolymer") used in these examples have units of the following formula:



where R¹, R², R³ and R⁴ are methyl, X is 10 and Y is 6 and DP is defined in Table 1 and n is a value sufficient to give the molecular weight shown in Table 1.

Table 1. Silicone-polyamide Copolymers

<u>Copolymer #</u>	<u>#1</u>	<u>#2</u>	<u>#3</u>
Silicone DP	15	45	100
Molecular weight	125,100	85,600	96,260

In the following, specific examples of hair care and skin care compositions within the scope of the present invention are also set forth. These specific hair and skin care examples are illustrative in connection with the present invention, and are not limiting. In the following, as well as throughout the present disclosure, names utilized are the CTFA (Cosmetics, Toiletry and Fragrance Association, Inc.) names, as set forth in the CTFA International Cosmetic Ingredient Dictionary (4th Ed. 1991). Throughout the description of this invention chemical abbreviations and symbols have their usual and customary meanings. While particular

siloxane-based polyamides are disclosed or used in the following Examples, it is to be understood that other siloxane-based polyamides (for example, those made with a purified siloxane diacid, di-anhydride, diesters, or diacid chloride) may also be used and are within the spirit and scope of the invention.

EXAMPLE I

Hair Spray

Hair spray compositions were prepared from the following components utilizing conventional mixing techniques.

<u>Ingredients</u>	<u>Weight %</u>	
	<u>A</u>	<u>B</u>
Deionized Water	38.1	--
Ethanol (SDA 40)	1.0	47.5
Isopropanol	--	4.5
Cyclomethicone	54	38.1
Silicone Copolyol	0.5	0.5
Triisopropanolamine	0.4	0.4
Copolymer #3 of Table 1	6.0	--
Copolymer #1 of Table 1	--	3.0
Acrylate Copolymers Resin (Gantrez ES 425)		6.0

Gantrez ES 425 is available from ISP Corporation

These products are prepared by first dissolving the copolymer in the Cyclomethicone (A) or isopropanol (B) with stirring. The remaining ingredients are then added with stirring. The resulting hair spray compositions can then be packaged in a non-aerosol spray pump. Alternatively, the compositions can be combined with conventional propellants and packaged in an aerosol spray.

These hair sprays are useful for application to the hair to provide a styling and holding benefit, as well as sustained release of fragrance.

EXAMPLE II

Hair Conditioner

Hair conditioner compositions were prepared from the following components utilizing conventional mixing techniques.

<u>Ingredient</u>	<u>Weight%</u>			<u>Comp.</u>
	<u>A</u>	<u>B</u>	<u>C</u>	
Phase 1				
Copolymer #2 from Table 1	0.5			
Copolymer #3 from Table 1	--	0.5	0.5	
Amino Emulsion				4
Cyclomethicone	24.5	4.5	--	

Dimethicone, 10 cSt.	--	--	24.5	
Phase 2				
Deionized Water	69.7	89.7	69.7	92.3
Cetrimonium Chloride (Arquad 16-29)	0.3	0.3	0.3	
PEG 100 Stearate & Glyceryl Stearate (Arlacel 165)	1.0	1.0	1.0	1.0
Cetearyl Alcohol (Lanette Wax O)	2.5	2.5	2.5	1.0
Hydroxethyl Cellulose (Natrosol 250 MR)	1.50	1.5	1.5	1.5
Preservative				0.2

Natrosol™ 250 MR available from Hercules of Wilmington, DE

Lanette O available from Cognis Corp. of Hoboken, NJ

Arlacel™ 165 available from Uniqema of Wilmington, DE

Arquad 16-29, 29% active, available from Akzo Nobel Chemicals

Procedure:

Deionized water is added to the mixing vessel and heated to 75 °C. With moderate agitation, disperse the Hydroxyethyl Cellulose until fully dissolved. Decrease heat to 60°C and add Cetearyl Alcohol and Peg-100 Stearate & Glyceryl Stearate. Decrease heat to 40°C and add Phase 1. Mix for 5-10 minutes and allow cooling to room temperature.

Slightly bleached European human hair from International Hair Importer and Products Inc was used for testing the conditioners in Example II. A master hand of hair about eight inches in length was subdivided into a series of individual hair tresses. Each tress weighed about 2.5 grams. A 1/2 inch of the root end of the hair was trimmed and glued to a 2" X 2" plastic tab using DUCO CEMENT®. The cement was allowed to dry, and the hair tress was combed and trimmed to a length, which allowed six inches of hair to extend below the bottom of the plastic tab. A hole was punched in middle of tab ~ 1/4" from the top. Each tress was rinsed for 15 seconds under 40 C tap water. Using a pipette, 1.0 g of a 9% Sodium Lauryl Sulfate (active) solution was applied and lathered through the tress for 30 seconds. The tress was rinsed for 30 seconds under running water. Excess water was removed from the tress by passing the tress between the index and middle fingers. The tresses were placed on a tray covered with paper towels and dried overnight. Each tress was hand combed three times with the narrow teeth of an ACE® comb and evaluated using the INSTRON "WET" and the INSTRON "DRY" COMBING procedures.

For tests involving the rinse-off conditioner, the hair tress is rinsed with tap water for 30 seconds at 40°C. The test conditioner is applied to the tress in the amount of 0.8 g and the tress is stroked for 30 seconds. The tress is rinsed for 30 seconds under tap water at 40°C. The excess water is removed by pulling the tress through the index and middle fingers. The tresses are allowed to dry

separately on a paper towel, overnight at room temperature. The tresses are combed once before performing the Instron study.

INSTRON COMBING is an industry recognized test for determining hair conditioning by the ease of wet combing and the ease of dry combing. The test employs an INSTRON strain gauge that is equipped to measure the force required to comb the hair. Conditioning performance is based on the ability of a particular hair treatment formulation such as a shampoo or a hair conditioner to reduce the force required to comb the hair with the INSTRON strain gauge. The force is reported as Average Combing Load (ACL). The lower ACL value, the better the conditioning effect imparted by the formulation being tested. Typically, ACL baselines are initially established with "untreated " tresses that have only been washed with the Sodium Lauryl Sulfate solution. The effectiveness of a treatment can be expressed as the ACL of the treated tress or the % Reduction in ACL which is calculated by $((\text{untreated hair ACL} - \text{treated hair ACL}) / \text{untreated hair ACL}) * 100$.

According to the INSTRON WET COMBING method, the hair is first wet by dipping it in distilled water and then the hair is detangled by combing the tress three times. The tress is then retangled by dipping in distilled water three times. The excess water is removed by passing the tress through index and middle fingers twice. The tress is then placed on the hanger and INSTRON combed. The "retangle" and "Instron combing" steps are repeated until all data points are collected. An average combing force of three tresses is measured for each treatment.

According to the INSTRON DRY COMBING method, the hair is detangled by combing the tress 3 times. Then the hair is retangled by swirling the tress clockwise 3 times and counter clockwise 3 times. The tress is then placed on the hanger and INSTRON combed. The "retangle" and "Instron combing" steps are repeated until all data points are collected. An average combing force of three tresses is measured for each treatment. The results of the INSTRON DRY COMBING test conducted with the conditioners of the present invention showed that Formulation C gave equivalent performance to a formulation containing an Amino Emulsion, used in the hair care industry as a conditioning silicone polymer. In addition, the formulations containing the silicone-polyamide copolymers gave hair tresses having good shine.

This product is useful as a rinse off hair conditioner and the silicone-polyamide will provide thickening, a styling benefit, and sustained fragrance release.

EXAMPLE III

Shampoo Composition

A shampoo composition can be prepared from the following components utilizing conventional mixing techniques.

<u>Ingredients</u>	<u>Weight%</u>
<u>Styling Agent</u>	
Copolymers from Table 1	1.00
Cyclomethicone	9.0
<u>Premix</u>	
Silicone emulsion	1.0
<u>Main Mix</u>	
Ammonium lauryl sulfate	11.00
Cocamide MEA	2.0
Cetyl alcohol	1.0
Dimethicone copolyol	0.5
Water	74.5

This shampoo will be useful for cleansing the hair and for providing a styling benefit.

EXAMPLE IV

Sunscreen Composition

An oil-in-water emulsion can be prepared by combining the following components utilizing conventional mixing techniques.

<u>Ingredients</u>	<u>Weight%</u>
<u>Phase A</u>	
Water	82.9
<u>Phase B</u>	
Octyl Methoxycinnamate	7.50
Oxybenzone	1.00
Cetyl Palmitate	0.75
Dimethicone	1.00
Tocopheryl Acetate	0.10
Copolymers from Table 1	1.75
<u>Phase C</u>	
Water	2.00
Butylene Glycol	2.00
<u>Phase E</u>	
Cyclomethicone	1.00

This emulsion will be useful for topical application to the skin to provide protection from the harmful effects of ultraviolet radiation. The silicone-polyamide copolymer will provide wash off resistance to the sunscreen composition.

EXAMPLE V**Facial Moisturizer A**

A leave-on facial emulsion composition can be prepared by combining the following components utilizing conventional mixing techniques.

<u>Ingredient</u>	<u>Weight %</u>
Phase 1	
Dimethicone Copolyol DC 5225C	10.0
Dimethicone	10
Copolymer from Table 1	4.0
Phase 2	
Water	71.0
Glycerin	5.0

Stir the oil phase at 800 rpm until dispersed, and with mixing add the water phase over 10 minutes at 1376 rpm. Mix for an additional 10 minutes at 1376 rpm using a dual blade mixer.

This emulsion is useful for application to the skin as a moisturizer. The silicone-polyamide will provide thickening, durability and longer lasting fragrance release to the moisturizer.

Facial Moisturizer B

A leave-on facial emulsion composition was prepared by combining the following components utilizing conventional mixing techniques.

<u>Ingredient</u>	<u>Weight %</u>			
	<u>A</u>	<u>B</u>	<u>C</u>	<u>D</u>
Glycerin	5.0	5.0	5.0	5.0
#2 Copolymer from Table 1	4.0	--	4.0	--
#3 Copolymer from Table 1	--	4.0	--	4.0
Cyclomethicone	36.0	36.0	--	--
Dimethicone (10 cSt.)	--	--	36.0	36.0
Water	53.0	53.0	53.0	53.0
Sepigel 305	2.0	2.0	2.9	2.0

Sepigel 305 is available from Seppic

This product is prepared by first dissolving the copolymer in the cyclomethicone with heating and stirring. The remaining ingredients are then added with stirring at 1200 rpm using a dual blade mixer.

This emulsion is useful for application to the skin as a moisturizer. The silicone-polyamide will provide thickening, durability and longer lasting fragrance release to the moisturizer.

Sensory testing for skin feel attributes was performed on formulations A, B, C, and D according to ASTM Standards E 1958-98 (Standard Guide for Sensory Claim Substantiation) and E 253 (Terminology Relating to Sensory Evaluation of Materials and Products), and ISO Standard 6658 (Sensory Analysis- Methodology- General Guidance). The formulations containing the silicone-polyamide copolymers gave higher absorbency, lower wetness, and were thicker than the formulation without silicone-polyamide copolymer.

EXAMPLE VI

Color Foundation

A color foundation composition containing a pigment blend was prepared by combining the following components utilizing conventional mixing techniques.

<u>Ingredient</u>	<u>Weight %</u>
<u>Phase 1</u>	
Pigment Blend (See below)	32.9
Dimethicone Copolyol	6.8
#3 Copolymer from Table 1	10.0
<u>Phase 2</u>	
Water	49.2
Sodium chloride	0.9
Tween 20	0.2

Pigment Blend:

<u>Ingredient</u>	<u>Supplier</u>	<u>Weight %</u>
Cyclomethicone	Dow Corning	50.00%
Titanium Dioxide	Cardre AS	13.16%
Red Iron Oxide	Cardre AS	11.41%
Yellow Iron Oxide	Cardre AS	18.26%
Black Iron Oxide	Cardre AS	7.17%

Pigment Blend Procedure:

1. Place cyclomethicone into blender.
2. Add titanium dioxide and mix by pressing the pulse button for 2 seconds for 15 seconds total.
3. Add red pigment and mix with pulse button several times. Repeat with each pigment color.
4. When all materials have been dispersed, mix on high and shred for 30 seconds to grind the pigments.
5. Place premix into a round glass jar and place on a pail roller for 6 hours.

Foundation Procedure:

1. Combine ingredients in Phase A, mix until uniform using a dual blade, turbulent style mixing action.
2. Combine the ingredients in Phase B in separate beaker, mix until uniform using a magnetic stirrer.
3. Increase mixing speed of Phase A to 1376 rpm and very slowly add Phase B. This addition should take 10 minutes.
4. Continue mixing for an additional 10 minutes.

Durability Test Method: Gardner Abrasion Tester

1. Cut collagen into 3.5" x 3" pieces, place one on each of the 3" x 2.5" polycarbonate blocks and put in the humidity chamber overnight. This chamber must be at a constant 98% relative humidity level.
 2. Remove collagen and block from chamber. Secure collagen to block with Scotch tape taking care not to place any on the top of the block's surface.
 3. Using a four-place balance, tare the balance and weigh the block and collagen. Record weight.
 4. Add approximately 1 gram of foundation to the collagen, beading it across the top of the block.
 5. Using a #8 Meyer rod, coat the collagen with the foundation by placing the rod on the bead of foundation and spreading it downward to the bottom of the block. The final coating weight should be approximately 0.2 grams. This operation may need to be repeated to obtain the proper coating weight. Remove any material from the sides of the block. Record sample weight.
 6. Clean the Meyer rod by wiping off excess foundation, rinse with isopropyl alcohol, and wipe with paper towel. Obtain a 500mL plastic graduated cylinder. Fill the cylinder with isopropyl alcohol and place the rod into the cylinder. Allow the rod to soak for several hours until free from any pigment. Wipe clean with a paper towel.
- Allow sample to dry. Record drying time. Drying times vary with different samples. Entire sample must be free from any wetness before testing.
7. Setup will include verifying that the software will take three readings, fifteen seconds apart. This can be done in the Read menu under "timed read method".
 8. To test the sample, Place the sample face down on the light source with the side that is labeled "Top" on the side away from the user.
 9. To begin testing, click on the "Read Sample" icon located in the toolbar. After three readings have been taken, it will ask the user to accept the data. Click on accept, type in a brief identification name for the sample and that the reading is at time zero. Press Enter.
 10. Remove the block and place it face-up on the Gardner Abrasion Tester with the side marked "Top" up making sure that the block is secure to the Velcro. Start the insulting block on the left side of the block with the Velcro strips facing downward. Depress the "power" button and press the "run" button. Allow the insult block to move across the sample and back twice. Depress the "power" button when the insulting block is on its way back during the second trip. Using two insults is the recommended amount for this test.

11. Remove the block from the abrasion tester and test the sample on the spectrophotometer as in part 8 above.
12. Repeat the insult and test procedure ten times. The number of insults, coating weight, and repetitions can be changed to fit the needs of the material being tested. This is up to the discretion of the operator.

This emulsion is useful for application to the skin as a color foundation. The silicone-polyamide copolymer #3 provided thickening and durability to the foundation, and should provide longer lasting fragrance release.

EXAMPLE VII

Lipstick

A lipstick composition containing a pigment blend can be prepared by combining the following components utilizing conventional mixing techniques.

White Ozokerite wax	4.00%
Candelilla Wax	11.00%
Octyldodecanol	25.00%
Petrolatum	4.00%
Lanolin Oil	2.00%
Avocado Oil	1.00%
Oleyl Alcohol	8.00%
Pigment Blend	6.10%
Copolymer from Table 1	4.0%

Pigment Blend:

Cyclomethicone		77.5
Titanium Dioxide (Dimethicone Treated)	Sun C47-4051	3.0
Red Iron Oxide (Dimethicone Treated)	Warner Jenkinson C9753	9.0
D&C Red #6 Barium Lake	Sun C19-012	6.5
D&C Red #7 Calcium Lake	Sun C19-011	4.0

Procedure:

1. Prepare pigment blend using blender to disperse pigments.
2. Heat all ingredients to 80°C while mixing slowly, taking care not to create a vortex.
3. Pour into lipstick mold and leave to set in freezer.
4. After 30-45 minutes, remove lipstick from mold and place in lipstick tubes.

This emulsion will be useful for application to the lips as a lipstick. The silicone-polyamide will provide thickening and durability to the lipstick.